## V. PRIVATE PAYORS[180]

93. For many of the reasons discussed above, Dr. Hartman's expectations theory fails to provide a foundation for liability and damages related to Class 3, consumers and TPPs who paid for PADs based on contracts expressly using AWP outside of the Medicare Part B context. In addition, Dr. Hartman's theory founders on the competition that exists among TPPs and physician providers in the negotiation of reimbursement rates. If TPPs had been able to negotiate lower reimbursement rates, presumably they would have done so. In fact, although TPPs were aware of the generally lower reimbursement rates being paid through Medicare Part B, they were still only able to negotiate reimbursement schedules that tended to exceed Medicare Part B rates. This section of the report provides further discussion regarding the information available to TPPs, the role of competition in the setting of reimbursement rates for PADs, and the broader objectives of TPPs when negotiating reimbursement rates for PADs.

### A. Information available

94. Plaintiffs' claims and Dr. Hartman's theory are predicated on the assumption that private payors were not aware of large differences between AWP and acquisition costs. Contrary to this assumption, however, TPPs—who can be sophisticated purchasing agents or may contract for such service through benefits consultants—had access to a wealth of information regarding pricing practices in the pharmaceutical industry throughout the class period. Some were purchasing PADs through other segments of their operations, such as a staff-model HMOs; others, such as CIGNA, were Medicare carriers; and all were or could have become familiar with the contracting practices of pharmaceutical manufacturers when faced with therapeutic or generic competition. A payor with concerns or curiosity regarding pharmaceutical acquisition costs and price concessions had numerous sources available to inform its reimbursement operations, including public studies of reimbursements and acquisition costs, price and reimbursement

[180] See Appendix C for a more extensive discussion of the information on pharmaceutical pricing that was available from non-government publications prior to and during the class period.

schedules released by the federal government, publicly broadcast addresses by the President of the United States, the business and popular press, policy discussions and debate regarding reimbursement methods for public programs (e.g., Medicare and Medicaid), and specialized market research and data sources regarding pharmaceutical prices. The abundance of information ensures that any payor exercising due diligence in the management of PAD reimbursements would be able to determine the availability and general magnitudes of price concessions by manufacturers.

95. I understand that one might question the extent to which the government studies were truly accessible to the TPPs at issue in this case. In fact, private payors tend to be aware of and track changes in reimbursement policies employed by public payors. This is not surprising as the public payors (Medicare, Medicaid, VA, and DOD) tend to be the largest single payors in the healthcare system. There are several prominent examples of how private sector payors have followed government programs in reforming reimbursement systems. For example, Medicare's prospective payment system ("PPS") for hospital care, implemented in 1983, bases reimbursements on diagnosis-related groups ("DRGs"). A wide variety of third-party payors adapted elements of this system for their own use over the next decade, including workers' compensation systems, more than one-half of the Blue Cross and Blue Shield Association member plans, many other commercial health plans, several self-insured employers, and a few employer coalitions.[181] Similarly, in 1993, after Medicare began implementing the Resource Based Relative Value System for procedures performed in a physician office, similar reimbursement systems were introduced as replacements for charges-based systems in one-third of the public and private payors surveyed.[182]

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181 Carter, Grace M. et al, "Use of Diagnosis-Related Groups by Non-Medicare Payers," *Health Care Financing Review*, Winter 1994, pp. 127–158 at 127.

182 McCormick, Lauren A. and Russel T. Burge, "Diffusion of Medicare's RBRVS and Related Physician Payment Policies," *Health Care Financing Review*, December 22, 1994, p. 159.

96. Many private payors also have adopted or adapted Medicare's HCPCS level II code infrastructure in designing their own reimbursement systems for PADs.[183] Some of these payors base PAD reimbursement directly on the Medicare system, including using the Medicare rates (or a percentage of these rates), HCPCS Level II codes, and RBRVS to process the claims.[184] Further, some private payors have expressed concern that their reimbursement rates would not be seen as competitive if they deviated from the traditional Medicare-based system. For example, Intermountain Health Care ("IHC") feels that market dynamics require it to maintain its reimbursements at levels which are 10 percent higher than those of Medicare Part B.[185] Finally, some private payors are evaluating a move to ASP-based reimbursement, following Medicare's lead under the MMA.[186]

97. Private payors also had access to the public press and its comments regarding pharmaceutical pricing and reimbursement. Throughout the class period, numerous national and regional outlets for public sector information discussed the role of AWP as a pricing benchmark and verified the existence of frequent discounting. For example, in a 1989 *Arkansas-Democrat Gazette* article, Bill McCutcheon, a regional administrator for HCFA, was quoted as saying, "Numerous studies and open admission by the people who publish those prices [AWPs] has shown that the average wholesale price doesn't represent the actual cost to pharmacies by any stretch of the imagination."[187] Similarly, a 1996 article

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183 See Deposition of Dan Dragalin, MultiPlan, September 17, 2004 ("Dragalin (MultiPlan) Deposition"), pp. 81-83; and Deposition of Mickey Brown, BCBS Mississippi, September 17, 2004 ("Brown (BCBS-Mississippi) Deposition"), p. 41.

184 Dragalin (MultiPlan) Deposition, pp. 47–48; Deposition of Eric Cannon, IHC Healthplans, September 13, 2004 ("Cannon (IHC) Deposition"), pp. 154–157.

185 Cannon (IHC) Deposition, p. 154.

186 In addition, by converting to an ASP-based system, private payors would minimize the disruption that might otherwise occur if medical publishers stop publishing AWP. First DataBank, for example, no longer publishes an AWP, instead relying on Average Benchmark Price ("ABP"). (See *The Prescription Drug Benefit Cost and Plan Design Survey Report*, The Pharmacy Benefit Management Institute, Inc., 2005, p. 8.) Eric Cannon testified that IHC Health Plans is now using R.J. Health as its source of reimbursement rates for PADs. (See Cannon (IHC) Deposition, pp. 135-136.)

187 "Pharmacists Face Big Losses under Proposal, Official Says," *Arkansas Democrat-Gazette*, March 23, 1989. Similarly, in the context of SADs, the *Lexington Herald-Leader* in 1987 quoted the comments of David Feinberg, a top Pennsylvania Medicaid official, that the Average Wholesale Price: "just doesn't mean anything. It has no connection to what pharmacists really purchase the

from *Barron's* noted that "[f]or many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60%-90% below the so-called average wholesaler price, or AWP, used in reimbursement claims."[188]

98. A diligent payor or other participant in the pharmaceutical industry also has additional sources of information available to evaluate manufacturer price concessions. Parties are able to purchase pricing data from established vendors. IMS Health ("IMS"), for example, is a recognized global supplier of pharmaceutical and healthcare data. During the class period, IMS provided a number of data products ("audits") that provided information regarding the existence of pharmaceutical price concessions.

99. Finally, in early 2002, the current litigation took shape.[189] The litigation announced that there were significant differences between AWP and acquisition costs and that different purchasers paid different prices. Accordingly, the fraud alleged by Plaintiffs, even if it existed (and I believe it did not), could not have persisted beyond these filings as Plaintiffs would have been aware of the existence of discounts from AWP.

100. Deposition testimony from payors and benefits consultants demonstrates an awareness of information that was publicly-available during the period of interest. Consider the following.

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drug for." (Miller, John Winn, "Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars," *Lexington Herald-Leader*, July 5, 1987, p. A1.)

188 Alpert, Bill, "Hooked on Drugs," *Barron's*, June 10, 1996, pp. 15–18. For a more complete list of examples, see Appendix C.

189 I understand that Plaintiffs filed their first complaint in this matter on July 16, 2002. Prescription Access Litigation filed a similar complaint on December 20, 2001. (See "Consumer Groups Charge Industry-Wide Price Manipulation—Over $800 Million in Illegal Profits from Medicare & Medicare Patients; Federal Lawsuit Charges 28 Drug Companies with RICO, State and Federal Anti-Trust, and Consumer Protection Violations," *PR Newswire*, Boston, December 20, 2001.)

- Gary M. Owens of Independence Blue Cross ("IBC") testified about the wealth of information available and for which he is responsible within the scope of his position.[190]

- Christopher Brecht, the Chief Operations Officer of third party administrator Carday Associates, Inc. ("Carday"), testified on behalf of Man-U Service Contract Trust Fund ("Man-U") and identified sources for information on the healthcare industry reviewed by Carday and the information provided by benefits consultant The Segal Company ("Segal").[191]

- Edward Kaplan, the national health practice leader at Segal, a benefits consultancy, testified that in addition to a library of relevant material in each Segal office and a system by which relevant information was directed to health practice managers, Segal has reviewed studies by government agencies (including the GAO, CMS, and the Agency for Healthcare Policy Research ("AHCPR")) since at least 1993.[192]

101. As noted above, in the discussion of Classes 1 and 2, there is no foundation for Dr. Hartman's theory that payors expected a "reasonably predictable" relationship between AWP and acquisition costs. The 1992 OIG report that Dr. Hartman cites concludes that "there is no single discount rate which can be applied to the AWP to provide a reasonably consistent estimate of the physician's acquisition

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190 "All of the knowledge that I acquire about pharmaceutical reimbursement, and for that matter managed care reimbursement, is within the scope of my job. Basically, that information can come in from any number of sources, including journals that may contain articles about how reimbursement is being performed, it can be through Internet updates or advisories, it can be through mailings or reading material that is forwarded to me either through the mail or from another colleague, it can be with my direct discussions with the management team and the pharmacy services department, it could be through personal encounters with other colleagues at IBC." (Owens (IBC) Deposition, p. 58.)

191 Carday's sources of information included "Various updates from consultants, the international foundation, Society for Professional Benefit Plan Administrators, and a periodical produced by Tolly International." (Deposition of Christopher Brecht, June 3, 2004, p. 19.)

192 Deposition of Edward Kaplan, National Health Practice Leader, Segal, July 12, 2004 ("Kaplan (Segal) Deposition"), pp. 71–72. AHCPR is now known as the Agency for Healthcare Research and Quality ("AHRQ").

cost ...."[193] Consistent with the OIG's conclusion, several payors have testified that they did not have consistent (or any) expectations about the relationship between physician acquisition costs and AWP when setting reimbursement rates. For example:

- IBC did not have any expectation as to the relationship between AWP and acquisition costs when setting the reimbursement rates for PADs;[194]
- Coventry Health Care's ("Coventry") reimbursement rates are unaffected by acquisition cost or consideration of physician profit margins;[195] and
- Anthem Blue Cross Blue Shield ("Anthem BCBS") does not include providers' acquisition costs for drugs in their determination of reimbursement rates.[196]

102. Nonetheless, Dr. Hartman claims to find further support for his 30 percent liability threshold among members of Class 3 by noting that there is approximately a 30 percent range in the "discounts" from AWP in reimbursement rates negotiated between payors and health care providers, as noted by contracts produced in this case and by a survey of contracts performed on behalf of MedPAC.[197] Rather than support his position, however, the comparison to contracted reimbursement rates demonstrates two inconsistencies in Dr. Hartman's approach.

103. First, Dr. Hartman fails to recognize that there is a difference between a range of expected price discounts (between manufacturers and providers) and the range of

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193 OIG November 1992, Appendix II.

194 Owens (IBC) Deposition, p. 162. In fact, before joining Delaware Valley HMO as its medical officer, Dr. Owens was a family practitioner. In his capacity as a sole practitioner, Dr. Owens expected to be reimbursed more than his acquisition cost for pharmaceuticals: "I wanted to be paid more for the drug than I paid for it, so that I would remain whole on administering the drug." (Owens (IBC) Deposition, p. 25.)

195 Deposition of J. Russell Hailey, Chief Pharmacy Officer and Vice President of Pharmaceutical Services, Coventry, August 4, 2004 ("Hailey (Coventry) Deposition"), pp. 151–152.

196 Spahn (Anthem BCBS) Deposition, p. 93.

197 MedPAC March 2003. This study relies upon a study performed by Dyckman & Associates for MedPAC, which was published in August 2003 as *Survey of Health Plans Concerning Physician Fees and Payment Methodology*.

expected contract rates (between payors and providers). Acquisition cost discounts and contracted reimbursement rates are separate concepts, relying on the interaction of different parties from the pharmaceutical industry and subject to different economic pressures. For example, consider an oncology facility with a world-class reputation. Such a facility might be expected to negotiate price discounts from manufacturers (perhaps through reputation effects or volume) and might also be expected to negotiate lucrative reimbursement terms from providers who value including this facility in a network of providers. In this situation, the acquisition cost and reimbursement rate discussions are correlated, but negatively! The acquisition cost is lower than average, the reimbursement rate is higher than average, and the outcome is determined by provider characteristics (i.e., reputation), not the payor's expectations about a relationship between AWP and acquisition cost.

104. Second, and even more compelling, Dr. Hartman's reference to a reimbursement range that extends up to AWP plus 15 percent[198] proves that factors other than expected acquisition cost affect negotiated reimbursement rates. Even if payors expected providers to have received no price concessions, contracts that reimburse providers in excess of AWP demonstrate that payors either choose to include other factors in their reimbursement decisions or that payors lack the negotiating power to require lower reimbursement rates.

### i. Industry structure and information

105. A number of payors are vertically integrated, that is, they have acquired or developed the capabilities of other services in the pharmaceutical reimbursement or distribution chain. There are five types of vertical integration of interest: mail order, specialty pharmacy or distribution, captive PBM, staff model HMO, and hospital ownership. When a payor undertakes such a business venture, it also informs itself of providers' drug acquisition costs and price concessions.

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198 Hartman Liability Report, ¶ 22 (c), which refers to Table 9-2 of the MedPAC June 2003.

106. Exhibit E provides a summary of those payors with vertical relationships of interest, identified either through publicly-available documents or through deposition testimony. Whether through operation of mail-order pharmacies, specialty pharmacies, captive PBMs, staff-model HMOs, or hospitals, these payors had direct evidence of acquisition costs and could have used such information in negotiation or plan benefit design. Nationally, these payors represent nearly 100 million insured lives, nearly 2 million in Massachusetts.

107. First, many payors—such as Aetna Inc. ("Aetna"), CIGNA, and WellPoint Inc. ("WellPoint")—provide their own mail-order pharmacy services.[199] By operating mail-order pharmacies, these payors have direct exposure to the pricing policies of manufacturers. The payors use their mail order capabilities and formulary controls to extract price concessions from manufacturers seeking to compete for an increased share of the prescriptions in a therapeutic category that will be dispensed through mail order. In addition, information gleaned through mail-order operations informs other operations. For example, acquisition costs from mail-order operations may be used in the calculation of TPP's MAC prices, providing a payor with mail-order operations additional insight into the acquisition costs of multi-source products and the potential cost savings from MAC operations.

108. Mail order operations are primarily oriented around SADs, but with respect to PADs, to the extent that these payors were not already aware of the price competition among manufacturers with competing pharmaceuticals, the experience with their mail order operations would make them aware. Further, some payors actually use courier services to deliver certain oncology medications to patients, who then carry the medications to the physician's office for

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199 In September 2003, Atlantic Information Services, Inc. ("AIS") reported the following mail-order script volumes for Quarter 2, 2003: Aetna Pharmacy Management, 4.6 million; CIGNA Pharmacy Management, 5.0 million; and WellPoint Pharmacy Management, 3.3 million. ("Mail-order Rates, Capabilities Foster Increased Competitiveness among PBMs," Drug Cost Management Report, September 12, 2003.)

administration.[200] Industry observers also have noted that the prevalence of PAD distribution through mail has been increasing since the site of care has shifted from the hospitals to physician offices and even home care.[201]

109. Second, some major payors—such as Aetna, Anthem BCBS, CIGNA, HealthNet Inc. ("HealthNet"), Humana Healthplan Inc. ("Humana"), Kaiser Permanente ("Kaiser"),[202] PacifiCare Health Systems Inc. ("PacifiCare"), United HealthCare Services Inc. ("UHC"), WellPoint, and a collection of Midwest Blue Cross plans—have gone beyond mail-order pharmacy and developed their own full PBM services.[203] In addition to direct purchasing for mail-order operations, payors with captive PBMs also extract price concessions from manufacturers by virtue of their control over the formulary.[204] Again, even if these payors only managed pharmacy benefits for SADs, the experience with their PBM operations would make them aware of potential price concessions with respect to PADs to the extent that these payors were not already aware of the price competition among manufacturers with competing pharmaceuticals.

110. Third, some payors have developed specialty distributor and specialty pharmacy operations for the management of PADs, including Aetna (Aetna Specialty Pharmacy, LLC), Anthem BCBS (Anthem Prescription Management, LLC) CIGNA (CIGNA Tel-Drug), Highmark BCBS ("Highmark") (Medmark

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200 March, Astara, "Brown Bagging Chemotherapy Drugs," *Oncology Issues*, July/August 2001, pp. 23–28 at 24.

201 "Chains Still Lead, But Food Stores, Mail-Order Deliver Hefty Gains," *Drug Store News*, May 21, 2001, accessed at http://www.findarticles.com/p/articles/mi_m3374/is_7_23/ai_75030573/print. This article quotes Doug Long, Vice President of Industry Relations at IMS Health: "Mail order drug sales through the institutional markets, such as oncology, dialysis and radiology clinics, are being driven by the switch from in-patient to out-patient care."

202 Kaiser includes Kaiser Foundation Health Plans, Kaiser Foundation Hospitals, and Permanente Medical Groups. See http://employers.kaiserpermanente.org/kpweb/structurekp/entrypage.do, accessed March 21, 2006.

203 See Exhibit E and the sources listed therein.

204 Many of these formularies explicitly include certain PADs, such as the anti-anemia and anti-emetic products, and some include anti-neoplastics. For example, BMS's VePesid is on the non-preferred tier of Cigna's three-tier formulary. (Accessed at https://secure.cigna.com/cgi-bin/health/sdrug_list.cgi.)

Inc./Fisher SPS), and WellPoint (PrecisionRx Specialty Solutions).[205] Through the operation of these capabilities, payors would be purchasing directly from manufacturers and negotiating with manufacturers to extract price concessions as the manufacturers compete for a greater share of the specialty pharmacy dispensing and reimbursement. In addition, the payor could also gather information on costs accruing to physicians dispensing PADs routed through the related specialty distributors.

111. Vendors of pharmacy benefit management services for PADs, known as specialty pharmacy programs ("SPPs"), became more prevalent over the course of the class period. In 1978, Caremark's predecessor Baxter Healthcare began to deliver hemophilia homecare.[206] In the early 1980s, Accredo's predecessor began to distribute clotting factor and Protropin, a human growth hormone.[207] A 2004 *Drug Cost Management Report* article confirms that payor interests in specialty pharmacy had increased in the last several years and reports that, "Of MCOs [Managed Care Organizations] responding, 80% said they had conducted a competitive procurement process for specialty pharmaceuticals during the past two years. These MCOs solicited bids from three to 11 specialty pharmacy vendors, with an average of five vendors included in the procurement process."[208] For example, Mike Beaderstadt of John Deere Health Care, Inc. ("John Deere") recalls that his company insisted that Remicade, Lupron, and Synagis be sourced from a specialty pharmacy because the specialty pharmacy would demand

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205 "Specialty Pharmacy Market Offers Expansion Opportunity for PBMs," *Drug Cost Management Report*, September 12, 2003. See also Exhibit E.

206 Caremark, "Caremark History," available at http://www.caremark.com/wps/portal/_s.155/3359?cms=CMS-2-003599 accessed September 8, 2005, ("Caremark 2005").

207 Accredo, "About Accredo: History," available at http://www.accredohealth.net/ahi/about/history.htm , accessed September 8, 2005, ("Accredo 2005").

208 AIS, "Survey Spots MCOs' Contracting Goals for Specialty Pharmacy," *Drug Cost Management Report*, July 30, 2004 ("AIS 2004"), pp. 1-2.

significantly lower reimbursement than would the physicians who purchased the drugs themselves.[209]

112. Fourth, in staff-model health maintenance organizations ("staff-model HMOs"), pharmacists and physicians are employees of the insurer, the pharmacies and medical facilities are owned by the insurer, and a captive PBM generally manages pharmacy benefits. As such these organizations purchase pharmaceuticals and negotiate with manufacturers competing for a larger share of the organization's prescription business. These organizations thus have full knowledge of the pricing practices of the manufacturers, at least as they apply to their organizations. Staff-model HMOs are also often part of larger TPPs that reimburse the PADs at issue through other types of managed care organizations.[210] Further, these organizations compete with other payors to provide healthcare benefits to employers and other organizations. As such, the effect of their knowledge of pharmaceutical pricing is reflected in the prices at which they are willing to offer their healthcare benefits package.

113. Finally, some payors have acquired part or full ownership of hospitals. IHC Health Plans' corporate parent owns 21 hospitals and a number of physician groups, and IHC Corporate Pharmacy Services purchases pharmaceuticals on their behalf.[211] Like staff-model HMOs, hospitals use their control over the pharmaceuticals dispensed in their facilities to negotiate price concessions from pharmaceutical manufacturers. Through ownership of hospitals and medical facilities, health insurers have direct information on the negotiation practices used by and price concessions available from pharmaceutical manufacturers.

114. Payors and other industry participants thus operated in an environment replete with information regarding the difference between acquisition cost and AWP, including government studies, public reports, the experiences of their personnel, and their experience in administering public programs or negotiating private

209 Beaderstadt (John Deere) Deposition, pp. 77–78.

210 Exhibit E identifies 13 TPPs with staff model HMO operations.

211 Cannon (IHC) Deposition, p. 24.

contracts with providers. Payors have demonstrated through deposition testimony and reimbursement policies that they were aware that the difference between acquisition cost and AWP varied greatly by drug, depending on competitive circumstances and drug type.[212] Similarly, information that was available to payors during the period of interest showed substantial variation in discounts for single-source PADs, with rates that exceeded the 30 percent liability threshold posited by Dr. Hartman (and were even higher and more variable for multi-source PADs). While it is unlikely that any payor had full information on all price concessions across all products or that any manufacturer made all payors aware of all price concessions for its products, nonetheless, as will be discussed below, full information was not necessary to secure efficient or competitive contracts for the reimbursement of PADs.

## B. Competition and negotiation among TPPs and physicians

115. Dr. Hartman asserts that payors would have necessarily negotiated lower drug reimbursement rates had they been aware of the difference between physician acquisition costs and AWP. I do not agree.

116. Payors and physician providers meet in the marketplace and negotiate over the fee schedule. The two parties have conflicting objectives. Payors compete with each other for access to physician providers but are interested in paying as little as possible, subject to the need to maintain the quality of their provider networks.[213] For example, Dr. Owens said he believed that competition among payors gave physicians leverage in their negotiations with payors, because physicians knew

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212 CIGNA, for example, altered the reimbursement terms for 13 PADs after it recognized that generic availability had reduced the acquisition prices. "Our change that we made was in reaction to the result of competitive market forces. Generic drugs were introduced that drove down the acquisition cost, the cost of the product in the marketplace." (Herbold (CIGNA) Deposition, p. 86.) Other payors, such as Anthem Prescription Management, recognized that therapeutic competition reduced SAD acquisition prices. (Deposition of Robert Bell, Director of Trade Relations, Anthem PM, December 1, 2004 ("Bell (Anthem PM) Deposition"), pp. 54–57.)

213 Note that this applies to public as well as private payors. For example, Medicare reimbursement reforms and proposals frequently generate discussion of whether healthcare providers would participate if reimbursements were lowered. See, for example, the discussion following passage of the MMA when some oncologists warned that "they may refuse altogether to treat Medicare patients ...." (Harris, Gardner "Among Cancer Doctors, A Medicare Revolt," *The New York Times*, March 11, 2004, pp. C1, C4).

that payors needed them in their networks.[214] Physician providers compete with each other for access to the payors' members but are interested in being paid as much as possible, subject to the number of members to whom they have access. Dr. Hartman does not articulate how improved knowledge regarding acquisition costs would influence the outcome of these negotiations. Furthermore, even under Dr. Hartman's expectations theory, payors participating in the negotiations would have no knowledge of the actual acquisition costs being paid by different providers and neither the payors nor the providers would necessarily know how those acquisition costs would evolve over the duration of the contract. Finally, the pharmaceutical reimbursement rate is only one element of the contracts negotiated between payors and providers.

117. As even Dr. Hartman notes, pharmaceutical price concessions depend upon the individual characteristics of buyers and sellers, and the negotiating position and abilities of the parties involved.[215] Accordingly, it must be the case that pharmaceutical purchasers do not negotiate with manufacturers by simply applying a standard, preordained discount to a reimbursement benchmark. Different purchasers may negotiate different prices for the pharmaceuticals at issue. Similar dynamics and conclusions apply to providers who negotiate with payors over reimbursement levels.

118. As a result, it is to be expected that the reimbursement rates ultimately negotiated may yield different profits per product and service at the time of signing the contract and over the course of the contract. The profits available to physicians will differ for products and services, and different physicians will realize different profits as a result of their reimbursement contracts and purchasing options and agreements.

119. Evidence produced in this case demonstrates that payors were aware of the variation in the difference between AWP and drug acquisition cost on a drug-by-

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214 Owens (IBC) Deposition, pp. 49-50.

215 Hartman Class Rebuttal, 2004, ¶ 54.

drug basis. Mike Beaderstadt, at John Deere, noted that AWP did not have any consistent relationship with actual acquisition cost.[216] Joe Spahn, Senior Health Care Consultant, agreed that Anthem BCBS had "no particular expectations" of providers' costs.[217] Despite their awareness of variations in acquisition cost, payors often negotiate a single reimbursement rate, expressed as a percentage of the benchmark AWP, for all PADs.[218] As a result, payors expect that there will be some drugs for which reimbursement is closer to or farther from the providers' acquisition cost.

120. Payors expect to be unaffected by the availability of greater information on acquisition costs. For example, David Morris, Manager, Pharmacy Management Department at Anthem BCBS, noted that reimbursement rates are determined by negotiation and what the market will bear, not acquisition cost.[219] Mr. Morris's representations were recently confirmed, as Virginia Oncology Associates P.C., the largest network of cancer specialists in Virginia, walked out of negotiations with Anthem BCBS in December 2005 after noting that Anthem's offer of reimbursement rates for more than 30 cancer drugs was not fair or adequate.[220] Similarly, James Messinger, Vice President of Managed Pharmacy Products at Union Labor Life Insurance Company ("ULLICO"), noted that more information on pharmacies' acquisition price would not affect reimbursement formulae or reimbursement payments.[221]

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216 Beaderstadt (John Deere) Deposition, pp. 72–73.

217 Spahn (Anthem BCBS) Deposition, pp. 97-98.

218 "From a global perspective, average wholesale price minus a set percent is what we look at from a global perspective. We don't get down to specific – specific by product, by product." (Deposition of Timothy Hopkins, Executive Director of Retail and Mail Order Operations, Anthem Prescription Management, November 30, 2004 ("Hopkins (Anthem PM) Deposition"), p. 77) See also Owens (IBC) Deposition, pp. 37–38: "Q. Is it your understanding that someone else at Independence Blue Cross engages in a line item by line item negotiation with doctors over the reimbursement under a fee schedule? A. No one ever does that."

219 Deposition of David B. Morris, Head of the Pharmacy Management Department, Anthem BCBS, January 5, 2005 ("Morris (Anthem BCBS) Deposition"), p. 69.

220 Connolly, Allison, "Va. Oncology Associates and Anthem Extend Talks," *The Virginian-Pilot*, January 4, 2006. The parties agreed to extend their previous contract until April 30, 2006.

221 Deposition of James P. Messinger, Vice President of Managed Pharmacy Products at ULLICO, October 22, 2004 ("Messinger (ULLICO) Deposition"), pp. 64–65.

121. As noted above, when negotiating with physician providers, payors focus on paying as little as possible, subject to maintaining a network adequate to the payor's needs, rather than calculating a specific physician's acquisition costs. Examples from the deposition testimony are as follows.

- Mr. Spahn of Anthem BCBS agreed that Anthem's biggest concern in negotiating with physicians was maintaining an adequate provider network.[222]
- Dr. Owens agreed that IBC intended to offer "sufficient reimbursement to enable them to retain their robust network" and that IBC had done so since 1991.[223] Dr. Owens also noted that IBC has had to increase reimbursement to physicians because of "market forces."[224]

122. In summary, payors negotiate reimbursement rates and other financial terms with providers to achieve established operating goals, including ensuring sufficient provider participation in healthcare networks, appropriately encouraging patient care to be delivered in the most efficient setting, and promoting the use of generic drugs. Payors and physician providers consider the full scope of the financial terms under negotiation when attempting to meet their objectives, and will trade gains in some financial areas for losses in others, so that the net terms of the negotiation are acceptable. As noted by Ms. Herbold of CIGNA, "The negotiation is completed in whole, so negotiating all the physicians' services." She agreed that a physician definitely could "accept a lesser reimbursement for pharmaceutical products and instead demand a greater reimbursement for a particular service."[225] As a result, even if it were the case that some payors considered or had expectations about the difference between AWP and acquisition

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222 "Q. In order to maintain that provider network, does Anthem need to offer reimbursement rates that are sensitive to the market's demands? A. Yes. Q. So when we're referring to market dynamics and competitive dynamics, what we're really talking about is Anthem's need to maintain an adequate provider network, correct? A. Correct." (Spahn (Anthem BCBS) Deposition, pp. 54–55.)

223 Owens (IBC) Deposition, pp. 104-105.

224 Owens (IBC) Deposition, pp. 193, 201–202.

225 Herbold (CIGNA) Deposition, pp. 28–29.

cost, they would also recognize that pharmaceutical discounts were just one component of a larger financial relationship with providers.

123. Agreements in which payors reimbursed at or in excess of AWP indicate that there are more financial interactions between payors and providers than are considered in Dr. Hartman's expectations model. Evidence from payors and other sources provide at least three reasons for this behavior, all of which are inconsistent with Dr. Hartman's expectations model. Reimbursement rates in excess of acquisition costs might indicate:

- That payors received significantly more favorable terms in other aspects of the agreement with providers (e.g., a lower fee schedule for physician services);
- That payors are reimbursing more than pharmaceutical costs through the reimbursement rate, the "cross-subsidization" issue discussed earlier in this report;
- That payors are at a competitive disadvantage in securing provider participation, perhaps as a result of advantages due to provider reputation or relative scarcity.[226]

124. Dr. Hartman's expectations model is inconsistent with each potential explanation of reimbursement rates in excess of acquisition costs. If such contracts indicate that the payor is including other factors in the reimbursement decision, then Dr. Hartman's expectation needs to include payors' expectations for those other factors to understand how much of the payor behavior is motivated by the alleged actions by pharmaceutical manufacturers. If such contracts instead indicate that the payor is at a competitive disadvantage and must pay higher rates to secure provider participation, then a payor's expectations of pharmaceutical discounts are irrelevant.

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[226] See, for example, Owens (IBC) Deposition, pp. 49–50.

### i. Disadvantages of transparency

125. Contrary to the premise of Dr. Hartman's expectations theory, knowing acquisition costs could only affect the outcome of payor-provider negotiations if the payor were previously operating inefficiently in maximizing profits or services. If payors are operating efficiently, they are either already forcing reimbursement rates down through the competitive process of negotiating provider contracts or there are other competitive factors that limit reimbursement reduction opportunities.[227] It is not evident that new information or expectations would provide the payors with additional negotiating leverage such that the costs of providing healthcare services would decline.

126. Not only would the arrival of additional information not provide a better negotiating position for payors, but it might actually harm those payors who have operated efficiently. For example, payors understand that increased price transparency could erode the competitive advantages they enjoy relative to other payors. Coventry, for example, considers its reimbursement rates to be trade secrets and feels that it would be competitively disadvantaged if forced to disclose its rates.[228] IBC, too, considers its rates to be confidential.[229] Similarly, with respect to generic SADs, Michael Baca, Executive Director of Financial Operations at HealthNet Pharmaceutical Services, described HealthNet's MAC methodology as "a highly confidential, proprietary piece of information that could really hurt our competitive situation if we were to disclose that."[230]

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227 This result is not sensitive to the profit status of the payor. There exists ample academic evidence that for-profit, non-profit, and not-for-profit entities are virtually indistinguishable in their efforts to maximize returns. Instead, the type of facility affects how those returns are dispensed. For example, see: Edward C. Norton and Douglas Staiger, "How Hospital Ownership Affects Access to Care for the Uninsured," *Rand Journal of Economics*, 1994, pp. 171–185; or Frank Sloan, Gabriel Picone, D Taylor, and Shin-Yi Chou, "Not-For-Profit Ownership and Cost and Quality of Care: Is There a Dime's Worth of Difference," in *Handbook of Health Economics*, Vol. 1, AJ Culyer and Joseph P. Newhouse (eds.), Elsevier, 2000, pp. 1141–1174.

228 Hailey (Coventry) Deposition, pp. 153-154. Mr. Hailey also testified that it is not Coventry's position that pharmaceutical manufacturers should disclose rebate and discount information. (Hailey (Coventry) Deposition, pp. 154–155.)

229 Owens (IBC) Deposition, p. 97.

230 Deposition of Michael Baca, Executive Director of Financial Operations, HealthNet, October 8, 2004, pp. 79–80.

### ii. Conclusions

127. Thus, in addition to its failure to account for the abundance of information available regarding acquisition costs and AWP, Dr. Hartman's expectations approach is inconsistent with the competition among private payors and physician providers as they negotiate reimbursement rates. Most notably, payors do not condition their reimbursement policies on expectations of providers' acquisition costs or the relation of those costs to the AWP. Further, many payors were ambivalent about whether such information would be useful, as such information did not affect the outcome of their reimbursement negotiations.

128. To the extent that payors develop expectations regarding the difference between AWP and average acquisition price, they would understand that the difference would differ by drug, incorporating considerations of therapeutic and generic competition. Nonetheless, payors generally negotiate reimbursement for the entire bundle of drugs and physician services, not each line item individually. As a result, payors expect that there will be great variation in how close their reimbursement rate approximates acquisition cost for each drug. Payors know and expect this to be the case.[231]

## C. Payors condone a profit on PADs

129. Health insurers compete for business—the provision of healthcare benefits to employers, health and labor funds, and even individuals. Health insurers compete based on benefit plan design, cost, and the breadth and quality of their network of healthcare providers. As a result, the commercial success of an insurer depends critically upon its ability to negotiate reimbursement contracts with health care providers at the lowest possible total cost while still offering a network of providers valued by the insurer's members.

130. There is also competition among providers for access to the members of the health insurer's plans. Where health insurers identify a network of preferred

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231 For instance, payors may not revise their reimbursement rates for a product when generic versions of the product become available.

providers, those providers wanting to participate in the network compete by lowering the price at which they are willing to offer their services. Reimbursement for PADs is one element of that price.

131. Competition among health insurers for members and among providers for access to patients leads to reimbursement contracts that are negotiated between parties with opposing interests in a marketplace where each party generally faces competition. This competition precludes excess profits beyond those that are attributed to a party's market position. Competition among health insurers implies that any excess profits that they could generate would be re-invested in lower premiums and/or more generous benefit designs. If a lack of competition results in some providers negotiating relatively lucrative reimbursement contracts, then any negotiated reimbursement for PADs, whether benchmarked to AWP or not, would generate the same result over time.

132. Payors and society benefit from provider incentives to seek out the lowest costs of providing quality healthcare services, even if providers pocket the savings. Accordingly, it is appropriate that there be profit opportunities for physicians with respect to PADs—this provides an incentive to seek out the lowest possible acquisition costs for the products they dispense. The payors benefit because the profits that providers anticipate lead to competition among providers to offer payors and their members greater services at lower total cost.

133. To manage effectively the costs of their health plans, payors must generally consider how changes to one aspect of a plan might affect the other aspects of the plan. Consistent with these principles, payors may consciously encourage one type of service in order to avoid incurring the larger costs associated with alternative types of services. For example, a patient who fails to maintain a routine drug therapy regimen for the control of high blood pressure may ultimately be hospitalized for a heart attack or stroke, dramatically increasing the total cost of patient care to the payor (and to the patient who co-pays part of the cost of care). To this end, it was in the interest of both public and private payors

to move patients from the high-cost hospital setting into the physician office. Profitable PAD reimbursement was one means of accomplishing that objective.

### i. Payors must attract and retain providers

134. It is important to understand the economic context within which payors and physicians negotiate. Specialist physicians, such as oncologists, sometimes have local market power and thus can insist on considerably higher pharmaceutical reimbursement rates in return for agreeing to contract with private payors.[232] As an example, IHC has had to pay rates greater than Medicare's because of the market dynamics and demands of the providers.[233] Additionally, Dr. Dragalin said that MultiPlan has developed a few different fee schedules for each geographic location in which they have members and added that they may even develop a unique fee schedule for a provider that they really want in their network.[234] In fact, in many rural areas where there is low managed care penetration and few physicians, physicians (in particular, certain specialties) routinely refuse to accept managed care payment rates.[235] In these contexts, having more information about prices would not tend to change the outcome of negotiations. Of course, in areas where specialist physicians do not have market power, competition between physicians to be included in payors' networks would act to decrease reimbursement rates, but additional information would not offer the payor any significant advantage in the negotiation.[236]

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232 See comment by Joseph Newhouse, Ph.D., MedPAC 2003 Public Meeting, p. 9; Rosenthal Liability Deposition, pp. 314, 316.

233 Cannon (IHC) Deposition, p. 154.

234 Dragalin (MultiPlan) Deposition, pp. 46-48.

235 Noether, Monica, Peter Rankin and Rhett Johnson, *Competition in Health Insurance and Physician Markets: A Review of "Competition in Health Insurance: A Comprehensive Study of U.S. Markets" by the American Medical Association*, Charles River Associates, April 2002 ("Noether, et al., 2002"), p. 15; Gaynor, Martin and Tami Mark, "Physicians Contracting with Health Plans, A Survey of the Literature," February 9, 1996, p. 3, available at http://lost-contact.mit.edu/afs/net/project/afs32/andrew.cmu.edu/heinz/wpapers/1996-7.pdf.

236 For instance, data from MGMA show that as the number of provider organizations, physician groups, and managed care competitors increase, physician compensation tends to decrease. See William Hoffman, "A Look at the Trends in Physician Pay—While Overall Pay Remains Flat, Doctor-Employees May Face Trouble," American College of Physicians, from ACP-ASIM Observer, February 2001, p. 5. See also Norman K. Thurston, "Physician Market Power –

135. Several factors contribute to the payor's incentive to build broad physician and pharmacy provider networks. First, private health plans are more appealing to an employer if they have networks that are broad enough to put providers in close proximity to employees, all other things being equal.[237] Second, many managed care plans seek to ensure access to quality care by offering a wide range of medical services in their provider networks.[238] For plans seeking to build a network offering a complete range of physician services, even very small groups of specialists are often essential since there are generally few substitutes for specialized physician services in local markets.[239]

136. Since private payors compete for employers' business partly on the breadth of their provider networks and public payors seek to assure access to care, all payors have strong incentives to recruit and retain provider participation in their networks. Provider flight would cause the payor to incur the costs of finding and recruiting replacement providers for their networks (which may result in higher insurance premiums) and would reduce patient access to and quality of care.[240] The payor's incentive to prevent provider flight is particularly acute for specialists such as oncologists, who are often in relatively short supply and for whose patients an interruption in treatment to accommodate a switch in providers may lead to extremely prejudicial outcomes.[241] Thus, in order to secure services,

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Evidence from the Allocation of Malpractice Premiums," *Economic Inquiry*, July 2001, pp. 487–498.

237 "Medicaid Confronts a Changing Manage Care Marketplace," *Health Care Financing Review*, Fall 2002, p. 19; Deposition of William Barre, Vice President of Strategic Network Development, MedImpact Health Systems, September 29, 2004 ("Barre (MedImpact) Deposition"), pp. 23–25.

238 "Survey of Health Plans Concerning Physician Fees and Payment Methodology," MedPAC study conducted by Dyckman & Associates, No. 03-7, August 2003 ("MedPAC Dyckman Survey August 2003"), p. 18.

239 Noether, et al. 2002, p. 18.

240 Noether, et al. 2002, p. 17.

241 The American Medical Association ("AMA") announced a physician shortage in June 2005 ("AMA Announces Physician Shortage," June 21, 2005, accessed at http://www.ama-assn.org/ama/pub/category/15241.html) that included evaluation of shortages in eight states, and found that in Massachusetts "[t]he physician labor market is under extreme stress." ("The Physician Workforce: Recommendations for Policy Implementation," *Report on the Council of Medical Education*, CME Report 8-A-05). See also Raja Mishra, "State's Patients Endure Long Wait," *The Boston Globe*, June 7, 2005, accessed at

prevent provider flight, and keep procedures out of the high-cost hospital environment, payors are willing to pay physicians higher reimbursement rates.[242] According to Dr. Gary Owens, competition among managed care entities for physicians allows physicians to negotiate higher reimbursement rates,[243] which may be reflected as spread on PADs. Dr. Dan Dragalin of Multiplan agrees that health plans often reimburse physicians for the cost of the drug plus a profit margin in order to keep physicians in the health plans' networks.[244]

## VI. FLAWS IN PLAINTIFFS' LIABILITY AND DAMAGES ANALYSES

137. It is my understanding that expert reports on damages, if required, are to be submitted at a later date. Nonetheless, as both the Hartman Liability Report and the Hartman Liability Report Supplemental encompass estimates of alleged damages, I offer the following critique of these calculations.[245] First, I address issues regarding Dr. Hartman's calculation of "spread." Second, I address the numerous ways in which Dr. Hartman fails to properly confine his analyses to the classes at issue. I conclude that Dr. Hartman's methodology inappropriately finds liability where none may exist and results in inflated estimates of alleged damages.

### A. Calculating "spread"

138. Dr. Hartman commits four types of errors when calculating "spread." Each of these errors results in inappropriate conclusions on alleged liability and inflated estimates of alleged damages. First, Dr. Hartman fails to calculate the Hartman ASPs appropriately by including in his calculations the effect of sales to classes of

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http://www.boston.com/yourlife/health/other/articles/2005/06/07/study_details_ills_of_doctor_shortage/?page=full.

242 Spahn (Anthem BCBS) Deposition, pp. 54–55.

243 Owens (IBC) Deposition, p. 39–41.

244 Dragalin (MultiPlan) Deposition, pp. 15–16.

245 I note that Dr. Hartman does not appear to have an opinion regarding which of his two sets of calculations regarding alleged liability and damages is correct. (Hartman Liability Deposition, pp. 662–663.) The differences between the alleged damages (all classes) estimated in the two reports is substantial, the total damages figure in the Hartman Liability Report Supplemental is more than $485 million higher than in the Hartman Liability Report, exclusive of prejudgment interest, even though no new data are being considered. (Tables 1a. in each of the reports, page 2 and 3 respectively.)

trade that are not at issue in the litigation. This error is principally manifest in the calculations supporting the Hartman Liability Report Supplemental. Second, Dr. Hartman fails to consider variation in AWP. For instance, to the extent that the AWP differs among the pricing publications, the determination of alleged liability and damages can depend upon the pricing publication chosen for the AWP. Third, with respect to Class 3, Dr. Hartman assumes that TPPs reimburse at 97.5 percent of AWP. The reimbursement rate negotiated between payors and providers, however, varies over time, by payor, by provider, and by product. Further, Dr. Hartman makes no attempt to assess the extent to which reimbursement rates would increase for related services and administration fees if the reimbursement rate for PADs were to decline. Fourth, with respect to Medicare Part B, Classes 1 and 2, Dr. Hartman incorrectly assumes that reimbursement was intended to be equal to acquisition cost.

### i. Calculation of Hartman ASPs

139. As I understand Dr. Hartman's methodology, he intends to use his calculation of the Hartman ASPs as a measure of the average acquisition cost for the products dispensed to class members. Accordingly, the calculation of Hartman ASPs should only consider those sales of products that ultimately were dispensed to class members. As an example, Exhibit F provides a general approach to the calculation of physician acquisition cost.

140. The approach that Dr. Hartman uses to calculate the Hartman ASPs for the Hartman Liability Report does not differ substantively from the approach identified in Exhibit F. The calculation of Hartman ASPs for the Hartman Liability Report Supplemental, however, appears to add four categories of sales that are not at issue in the litigation: sales to hospitals, staff-model HMOs, community healthcare clinics, and animal health/human products. These categories of sales were appropriately excluded from the calculation of the Hartman ASPs for the Hartman Liability Report and Dr. Hartman offers no rationale for why they are included in the calculation of ASPs for the Hartman

Liability Report Supplemental, other than a request from counsel.[246] As a result, Dr. Hartman inappropriately concludes on liability in the Hartman Liability Report Supplemental and generates inflated estimates of alleged damages.

### ii. Variation in AWP

141. Apparently, Dr. Hartman relies upon the AWPs of a single pricing publication,[247] despite evidence that, prior to 2003, there was substantial variation among reimbursement rates calculated by different Medicare carriers and his own evidence that calculated spreads depended on the AWP source.[248] Regarding Medicare Part B, an OIG report from December 1997 noted that,

> "For some drug codes, the differences in allowed amounts were significant. Carriers' allowed amounts varied even for single-source drugs where the reimbursement rate is based on only one AWP. … For the first quarter of 1995, providers in one State were receiving 20 percent more in reimbursement than providers billing the same drug code in another State."[249]

142. Additionally, in a report released in January 2001, the OIG noted that for J0640 (leuprolide acetate, sold by Tap Pharmaceutical Products, Inc., as Lupron), the difference between the minimum and maximum reimbursement rates was in excess of 100 percent and that for J9000, a drug that is at issue in this case (doxorubicin hydrochloride, sold by BMS as Rubex), the difference was nearly 38 percent.[250]

143. Regarding private payors, an August 2003 report prepared for MedPAC noted that "The AWP itself can vary substantially between Red Book and First DataBank, so

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246 Hartman Liability Deposition, pp. 647–648, 655–658, 663. In fact, Dr. Hartman testified that the Hartman ASPs calculated for the Hartman Liability Report are reflective of the acquisition costs of physician providers. (Hartman Liability Deposition, pp. 1300–1301.)

247 To my knowledge, Dr. Hartman has not provided the documents from which his AWPs were taken.

248 In footnote 59 of the Hartman Liability Report, Dr. Hartman notes that AWPs for Taxol and Blenoxane differ between the Red Book and First DataBank. The Single Drug Pricer, implemented by CMS on January 1, 2003, was intended to eliminate the variation in Part B reimbursement rates across carriers. (CMS Program Memorandum, Intermediaries/Carriers, Transmittal No. AB-03-047, *Single Drug Pricer (SDP) Clarifications*, April 18, 2003.)

249 OIG December 1997, p. 9.

250 OIG January 2001, Table 2, p. 9.

the payment to physicians depends on which source the payer uses. One respondent provided an example where the First DataBank AWP was $62 and Red Book AWP was $325."[251] To the extent that Dr. Hartman's conclusions regarding alleged liability and damages depend on which pricing publication's AWP he chooses to use, the result would appear to be capricious and lack the appropriate foundation for an expert opinion.

### iii. Rationale for reimbursement in excess of acquisition cost

144. To calculate damages for Class 3, Dr. Hartman assumes that TPPs reimburse at 97.5 percent of AWP for the products at issue.[252] This assumption, however, ignores the rationale behind the reimbursement rates that were negotiated between payors and providers. These rates vary over time, by payor, by provider, and by product.[253] Further, Dr. Hartman makes no attempt to assess the extent to which Medicare Part B or TPP reimbursement rates would increase for related services and administration fees if the reimbursement rate for PADs were to have declined as he suggests would have been the case.

### iv. Medicare Part B expectation of reimbursement

145. With respect to Medicare Part B, Dr. Hartman incorrectly assumes that reimbursement was intended to be equal to acquisition cost, from the start of the class period through 2003.[254] I am not aware of any rationale that would support this assumption.[255]

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251 NORC Report 2003, p. 12.

252 Hartman Liability Report, ¶30 (b). Parenthetical omitted. The 97.5 percent is based on the results of the Dyckman Report which, for 2002, found that 7 plans reimburse at 87.5 percent of AWP, 8 plans reimburse at 95 percent of AWP, 10 plans reimburse at 100 percent of AWP, 5 plans reimburse at 105 percent of AWP, and 2 plans reimburse at 112.5 percent of AWP. ("Health Plan Payment For Physician-Administered Drugs," MedPAC, Prepared by Zachary Dyckman and Peggy Hess, Dyckman & Associates, July 2003 ("Dyckman July 2003"), p. 3.)

253 For instance, Jill Herbold noted that CIGNA's reimbursement rate was "typically 15 percent" below AWP, while some J-codes were reimbursed at "up to 45 percent below AWP" and others were reimbursed at AWP. (Herbold (CIGNA) Deposition, p. 21.) The Dyckman Report itself notes that: "… one plan reported using a combination of outdated AWP prices and prices that are selectively updated based on provider complaints." (Dyckman July 2003, p. 3.)

254 Hartman Liability Report, ¶ 19 (referencing Hartman Class Declaration, ¶ 33 (b)). I note that Dr. Hartman expressly denies an opinion with respect to this assumption. (Hartman Liability

146. For the Hartman Liability Report, an allegation of liability with respect to Classes 1 and 2 is made only if the 30 percent liability threshold is surpassed. Nonetheless, in those circumstances where there is an allegation of liability, the Hartman Liability Report presents an estimate of alleged damages that is based on the assumption that reimbursement was always intended to be equal to acquisition cost. As a result, the estimates of alleged damages in the Hartman Liability Report are grossly overstated.

147. For the Hartman Liability Report Supplemental, however, an allegation of liability with respect to Classes 1 and 2 is made whenever there is a difference between the Hartman ASP and the AWP. Thus in all product-years prior to 2004, the Hartman Liability Report Supplemental presents an estimate of alleged damages that is based on the assumption that reimbursement was always intended to be equal to acquisition cost. As a result, the alleged incidence of liability and the estimates of alleged damages are grossly overstated in the Hartman Liability Report Supplemental.

## B. Exclusions from liability

148. Dr. Hartman uses his 30 percent liability threshold to determine alleged liability. Throughout this report I have discussed the flaws in Dr. Hartman's expectations theory and the considerable amount of information that existed regarding the extent of the differences between acquisition cost and AWP. In my opinion, Dr. Hartman's expectations theory is seriously flawed and there is no basis to support his 30 percent liability threshold. Further, in Dr. Hartman's assessment, liability exists or persists even if payors understand pharmaceutical pricing and discounting; liability only ends when payors convert to a reimbursement system

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Deposition, pp. 879–882; Hartman Liability Deposition, pp. 924–925, 928–931; and Hartman Liability Deposition, pp. 1250–1251.)

255 Hartman Liability Deposition, pp. 876–901, 913–933, and Hartman Liability Deposition Exhibits 38–43.

not based on AWP.[256] As a result, Dr. Hartman attempts to absolve payors of responsibility in acting on known information.

149. To the extent that Dr. Hartman's theory can support any finding of liability (and I believe that it cannot), then adjustments must be made to account for several instances where liability has improperly been alleged and the consequent estimate of damages has been inflated. These adjustments include the need to address Dr. Hartman's failure to account for product sales that are excluded by the class definition, his failure to exclude reimbursements by TPPs that were aware of pharmaceutical pricing behavior based on their actual purchase or contracting for pharmaceuticals, and his speculation with respect to missing data.

### i. Medicaid enrollment

150. Dr. Hartman uses data from the National Ambulatory Medical Care Survey ("NAMCS") to apportion the sales of the drugs at issue to Medicare (Sub-Classes 1 and 2), Non-Medicare (Sub-Class 3), and Non-Class Sales (or Excluded).[257] Dr. Hartman uses the survey responses regarding the payer to classify the respondents: Medicare is Medicare; Non-Medicare is Self Pay, Workers Comp, and Private Insurance; and Non-Class/Excluded is Medicaid, Department of Defense, Other Government No Charge, and Government-Related Private. Dr. Hartman, however, presents no NAMCS data for fourteen of the products at issue.[258] In ten of these instances, Dr. Hartman arbitrarily assumes that half the

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256 Hartman Liability Deposition, pp. 800-801. Note, however, that Dr. Rosenthal commented that: payors lack the market power to implement a reimbursement system based on acquisition cost; she does not have an opinion about whether payors wanted to reimburse at acquisition cost; movement to a new reimbursement system was infeasible and costly; and no payor wanted to be the first to change reimbursement methods. (Rosenthal Liability Deposition, pp. 101-105.) Further, I note that Dr. Rosenthal attributes the lack of movement away from AWP-based reimbursement to feasibility and computer programming requirements, neither of which is related to knowledge of pharmaceutical pricing, and that Dr. Rosenthal neither reviewed documents related to payors nor discussed with payors the feasibility of adopting an alternative reimbursement system. (Rosenthal Liability Deposition, pp. 104-105, 111.)

257 Hartman Liability Report, p. 43. I note that NAMCS did not include oncologists as a specific category of physician until this 2006. (National Center for Health Statistics, Welcome NAMCS Participants, January 11, 2006, accessed at http://www.cdc.gov/namcs/.)

258 These are albuterol, Blenoxane, Etopophos, Myleran, Paraplatin, perphenazine, Proventil, Pulmicort, Remicade, Rubex, Temodar, Tequin, Ventolin, and VePesid. (Hartman Liability Report, Exhibit J.7.a.)

utilization was for members of Classes 1 and 2 and half the utilization was for members of Class 3. Ostensibly on the basis of "industry knowledge," Dr. Hartman assumes that for three of these products 75 percent of the utilization was for members of Classes 1 and 2 and 25 percent of the utilization was for Class 3; for the last product, Dr. Hartman assumes that 10 percent of the utilization was for members of Classes 1 and 2 and 90 percent of the utilization was for Class 3.[259] Medicaid, however, accounts for up to 18 percent of utilization for those products on which NAMCS data are presented. It is not reasonable to assume that there were no sales of these fourteen drugs to Medicaid recipients during the class period. The effect of Dr. Hartman's arbitrary assumption is to inflate his estimate of alleged damages.

### ii. Flat and uncollected co-payments

151. Dr. Hartman fails to account for the presence of flat and uncollected co-payments among the members of Classes 1 and 3. Flat co-payments are principally an issue for Class 1 as not all Medicare beneficiaries receive outpatient health insurance through Medicare Part B. Some Medicare recipients are members of managed Medicare plans, known during the class period as Medicare Risk, Medicare+Choice, Medicare Part C, or Medicare Advantage plans. In managed Medicare plans, as in conventional managed care plans, members pay flat co-payments rather than the 20 percent coinsurance rate for traditional Medicare Part B. Dr. Hartman overstates his estimate of alleged damages for Class 1 by failing to deduct for the prevalence of managed Medicare plans.

152. With respect to uncollected co-payments, studies have found that between 20 and 30 percent of the co-payments due from Medicare Part B recipients are uncollected.[260] For instance, as noted above, the COA estimated that 25.3 percent

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259 Hartman Liability Deposition, pp. 1120–1124.

260 "Oncologists now absorb from 20% to 30% of bad debts resulting from patient's inability to pay co-payments. These patients continue to receive their cancer care regardless of their account status." (Holcombe, Dawn G., "The Evolution of Community Oncology Care and its Threatened Extinction Due to Federal Private Payment Reform," American College of Medical Practice Executives Paper (Medical Group Management Association Article Archive), September 2004.)

of Medicare co-payments are written off as bad debts.[261] As a result of Dr. Hartman's failure to account for uncollected co-payments, his estimates of alleged damages are overstated.

### iii. Alternate benchmarks and capitated contracts

153. In assigning liability and calculating damages for Class 3, Dr. Hartman fails to account for payors' use of contracts that did not rely on AWP during the class period. For example, Michael Mulrey, noted that BCBS-MA reimbursed PADs at usual and customary ("U&C") rates until 1995.[262] Deborah Devaux, also of BCBS-MA, noted that several Massachusetts-area insurers, including Fallon Community Health Plan, Rhode Island Group Health Association (later acquired by Harvard Community Health Plan), and BCBS-MA, had capitated contracts.[263]

### iv. Purchases by TPPs

154. For Class 3, Dr. Hartman concedes that payors who purchased drugs directly from manufacturers were aware of acquisition costs.[264] Based on Exhibit F, payors with direct acquisition cost information account for nearly 100 million insured lives nationally (roughly 50 percent) and more than 2 million insured lives in Massachusetts (almost 75 percent). By not excluding all sales reimbursed by TPPs that purchased the drugs at issue, Dr. Hartman errs by inflating his estimate of alleged damages.

### v. Missing data

155. Dr. Hartman lacks data on which to base damages for a number of years for a number of drugs. Dr. Hartman speculates with respect to alleged liability and damages by extrapolating or interpolating based on the data. I note that where data were available in consecutive years, Dr. Hartman finds that his allegation of

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261 COA 2004c, footnote 2.

262 Deposition of Michael T. Mulrey, Manager, Provider Reimbursement, BCBS, January 5, 2006 ("Mulrey (BCBS-MA) Deposition"), pp. 57-58.

263 Deposition of Deborah Devaux, Senior Vice President for Health Care Contract Management, BCBS-MA, March 9, 2006 (rough draft) ("Devaux (BCBS-MA) Deposition"), pp. 19, 20-21, 24, and 26-27,

264 Hartman Liability Deposition, pp. 1013-1016, 1024-1025.

liability and his estimate of alleged damages varies over time. Accordingly, there should be no presumption of alleged liability or damages in other periods. For example, Dr. Hartman estimates alleged damages (and hence assumes liability) for Navelbine, a GSK product, for 1995 and 1996 that are equal to his estimate of alleged damages for 1997. However, Dr. Hartman does not find liability for Navelbine in 1998, calling into question his speculation regarding alleged liability and damages for 1995 and 1996, based on his finding of alleged liability and his estimate of damages for 1997 alone. As to speculation regarding damages in 2003 and 2004, Dr. Hartman apparently fails to consider that the filing of the litigation in 2002 and thus the notification of the alleged pricing practices would presumably eradicate any pretence of fraud.

### vi. Composition of Class 1

156. In calculating damages for Classes 2 and 3, Dr. Hartman first calculates damages on a national basis and then uses data on the national distribution of PAD sales to allocate damages for Massachusetts TPPs (Class 2 and part of Class 3) and non-Medicare Massachusetts residents (the remainder of Class 3). Dr. Hartman, however, fails to adjust his estimate of alleged damages for Class 1 due to the 12 states that were excluded from class certification.[265] As a result, Dr. Hartman's estimate of alleged damages is overstated.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on March 22, 2006.

Gregory K. Bell, Ph.D.

[265] Residents of Alabama, Alaska, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Montana, and Virginia are excluded from Class 1, as are all Medicare beneficiaries who paid flat co-payments or who were or had the right to be fully reimbursed for their co-payments. (Class Certification Order, pp. 1–3.)

# APPENDIX A: INFORMATION ON PHARMACUETICAL PRICING FROM GOVERNMENT SOURCES

1. This appendix reviews many of the statements from governmental sources regarding the acquisition costs and reimbursement rates for pharmaceuticals. The primary focus is statements made with respect to Medicare Part B drugs, which are primarily physician-administered drugs ("PADs"). In addition, I review some of the comments related to the Medicaid prescription drug program, which primarily covers self-administered drugs ("SADs"), and other government programs that involve prescription drugs. Included in this review are comments expressing how information gleaned from one program informs thinking about another program.

## I. 1960s

2. In May 1967, John Gardner, the Secretary of Health, Education, and Welfare ("HEW"),[1] established a Task Force on Prescription Drugs, whose charge was to "[u]ndertake a comprehensive study of the problems of including the cost of prescription drugs under Medicare."[2] In an August 1968 memorandum, Irwin Wolkstein, Assistant Director, Division of Policy and Standards, HEW, criticized reimbursement that was based on a pharmacy's actual acquisition cost, saying that auditing would be expensive as well as "... incapable of accurate finding in a field where prices vary in the course of a year and rebates of various kinds are common."[3] In addition, he wrote, "A proposed alternative acquisition cost basis is the Red book [*sic*] – a listing of prices of manufacturers which is often violated by volume and other discounts to [*sic*] which would be subject to abuse by manufacturers setting prices high to advantage retailers."[4]

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1 HEW is now known as the Department of Health and Human Services ("DHHS").

2 U.S. Department of Health, Education, and Welfare, Task Force on Prescription Drugs, Background Papers, *The Drug Makers and the Drug Distributors*, December 1968, p. viii.

3 Memorandum from Irwin Wolkstein, Assistant Director, Division of Policy and Standards, HEW, to Joseph A. Higgins, Drug Task Force, *et al.*, August 6, 1968, p. 1.

4 *Ibid.*

3. In their final report in 1969, the Task Force considered four alternative bases for reimbursement for product costs, namely: actual acquisition cost, as verified by audit; 'usual and customary charges;' listed wholesale price; and fixed program payment.[5] In their discussion of using listed wholesale price, they point out that "… these listed prices rarely have any realistic relationship with actual acquisition costs."[6] The assumption behind consideration of this method was that "… any losses incurred by the program as a result of basing reimbursement on listed wholesale costs would be made up to the program in savings on auditing and other administrative costs."[7] The Task Force opined that the *Red Book* and *Blue Book* should not be used as the sole determinant of wholesale prices and that price listings should be compiled and revised frequently.[8]

## II. 1970s

4. Based on "[s]tudies of drug prices in the multiple-source market [that] indicate that savings of 22 to 36 percent would result from the dispensing of lower cost equivalent products,"[9] HCFA established the Maximum Allowable Cost ("MAC") program in 1974. This program limited reimbursement for multiple-source drugs to the lowest price at which chemically equivalent drugs are generally available.[10]

5. HEW recognized that published wholesale prices (i.e., AWPs) for the single-source drugs not covered under the Federal MAC policy were higher than

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5 "Final Report," Task Force on Prescription Drugs, February 7, 1969, reproduced in Prescription Drugs under Medicare: The Legacy of the Task Force on Prescription Drugs, Part 1, *Journal of Research in Pharmaceutical Economics*, Volume 10 Numbers 2/3 ("Task Force Report 1969"), pp. 146-147.

6 Task Force Report 1969, p. 148. At p. 147, the Report also states, "Under the pricing system now prevalent in the drug industry, the published wholesale price of a drug product is subject to a complex system of frequently changing discounts, including discounts based on the purchase of other drug products, and cumulative discounts based on volume that may be computed after the end of the accounting year."

7 Task Force Report 1969, p. 148.

8 Task Force Report 1969, p. 148.

9 39 Fed. Reg. 40303 (November 15, 1974).

10 39 Fed. Reg. 40303 (November 15, 1974).

what providers actually paid.[11] Under Medicaid, state agencies were free to determine their drug reimbursement policies, and HEW noted that there were a number of methods in use stating, "Some States reimburse providers on the basis of published wholesale prices; others pay on the basis of published prices less a volume discount to the program; still others pay the actual cost to the provider. Similar inconsistencies exist in other Department supported programs."[12]

6. In comments reported in the Federal Register on July 31, 1975, the Secretary of HEW described his position regarding the use of AWPs as a proxy for actual acquisition cost, stating,

> "The Secretary disagrees, however, that average wholesale price should be used as the basis for 'actual acquisition cost' determinations. Average wholesale price is not currently determined by surveying drug marketing transactions (i.e., by determining the actual price a pharmacist pays to a manufacturer or wholesaler for a particular drug product), and thus published wholesale prices often are not closely related to the drug prices actually charged to, and paid by, providers."[13]

7. Reimbursement based on actual acquisition cost had been abandoned due to "widespread opposition [due] to the potential difficulties pharmacists would incur in recordkeeping and invoicing procedures and the administrative problems of tracking deferred and cumulative discounts to pharmacists on their drug purchases."[14]

## III. 1980s

8. In 1984, the OIG issued a report on Medicaid prescription drug costs that stated, "Excessive payments are being made nationwide for the ingredient cost of prescription drugs under the Medicaid program."[15] The OIG found that most state

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11 39 Fed. Reg. 40303 (November 15, 1974).

12 39 Fed. Reg. 40303 (November 15, 1974).

13 40 Fed. Reg. 32284 (July 31, 1975) at 32293.

14 HCFA, *EAC Survey Report, California Medi-Cal Program*, EAC Patrol Initiative, 1986 ("EAC Patrol Initiative 1986"), p. 1.

15 OIG, *Changes To The Medicaid Prescription Drug Program Could Save Millions,* A-06-40216, 1984 ("OIG 1984"), p. 3.

Medicaid programs continued to reimburse at AWP.[16] According to the OIG, AWP was not an adequate estimate of prices providers paid, as AWP represented a list price and did not reflect discounts, rebates or free goods that appeared on pharmacists' invoices.[17] HCFA agreed with the OIG's observations that AWP was not the best estimate of actual acquisition cost, but noted that replacing AWP, as was proposed by the OIG, was not economically feasible at that time.[18]

9. During discussion of issues related to Medicare outpatient drug coverage in 1987, the GAO was asked how lessons learned from HCFA's experience with Medicaid prescription drugs could be used in designing a program for Medicare.[19] The GAO recognized that the AWPs listed in the *Red Book* and *Blue Book* overstated the actual acquisition cost of drugs.[20]

10. In August 1989, the Senate Special Committee on Aging published a Majority Staff Report that said, "DVA [Department of Veteran Affairs] achieves an average discount of 41% off the manufacturer's published 'Average Wholesale Price' (AWP) for single source drugs (those still under patent), and an average of 67% off the published AWP for multiple source drugs."[21] The report also stated, "Hospitals, Health Maintenance Organizations, and nursing homes that contract with wholesalers to purchase prescription drugs from a predetermined list are able to achieve discounts of up to 99% off the manufacturer's published 'Average Wholesale Price' (AWP), even for brand name products."[22]

11. In 1989, the OIG indicated that it continued to "believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or

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16 OIG 1984, p. 2.

17 OIG 1984, p. 22.

18 OIG 1984, pp. 24-25.

19 GAO, Testimony of Michael Zimmerman, *Issues Related to Possible Coverage of Outpatient Prescription Drugs Under Medicare*, Subcommittee on Health, Committee on Ways and Means, House of Representatives, GAO/T-HRD-87-15, June 2, 1987, p. 2.

20 *Ibid.*, p. 3.

21 "Prescription Drug Prices: Are We Getting Our Money's Worth?," A Majority Staff Report of the Special Committee on Aging, United States Senate, August 1989, p, 11.

22 *Ibid.*

Medicare programs,"[23] and recommended that for Medicare, "…HCFA consider using a reimbursement method other than AWP or [use a] discounted AWP similar to the Medicaid approach," because AWP was not a "meaningful payment level."[24]

## IV. 1990s

12. In June 1991, HCFA proposed basing Medicare Part B drug payments on 85 percent of the national AWP.[25] In its November 1991 final regulations, HCFA based reimbursement on the lower of the national AWP or the carriers' estimate of acquisition costs, noting that oncologists had responded that the 85 percent of AWP standard was inappropriate.[26] According to HCFA, "The thrust of most of the comments was that many drugs could be purchased for considerably less than 85% of AWP—particularly multi-source drugs—while others were not discounted."[27]

13. In 1992, the OIG reported on a study on the cost of dialysis-related drugs that found that "dialysis facilities purchase separately billable drugs significantly below the AWP."[28]

14. Also in 1992, the OIG reviewed physician costs for 13 high-dollar-volume chemotherapy drugs paid for by Medicare, finding that these chemotherapy drugs could be purchased at discounts to AWP and that AWP was "… not a reliable indicator of the cost of a drug to physicians."[29] A study of physician invoices

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23 OIG, *Use of Average Wholesale Prices In Reimbursing Pharmacies Participating In Medicaid and the Medicare Prescription Drug Program*, A-06-89-00037, October 1989 ("OIG Oct 1989"), p. 7.

24 OIG Oct 1989, p. 2.

25 56 Fed. Reg. 25792 (June 5, 1991).

26 CRS, Memo from Thomas Nicola (CRS) to the House Committee on Energy and Commerce regarding Regulatory and Legislative History of Medicare Drug Reimbursement Based on Average Wholesale Price, August 31, 2001 ("CRS Aug 2001"), pp. 2-3.

27 56 Fed. Reg. 59502 (November 25, 1991), at 59524.

28 Letter from Bryan B. Mitchell, Principal Deputy Inspector General, to William Toby, Acting Administrator, HCFA, attaching OIG, *Cost Of Dialysis-Related Drugs*, A-01-91-00526, October 1992 ("OIG Oct 1992"), p. 1.

29 OIG, *Physicians' Costs For Chemotherapy Drugs*, A-02-91-01049, November 1992 ("OIG Nov 1992"), pp. 1-2 and 5. As part of their study, the OIG staff interviewed *Red Book* officials, who

confirmed that physicians' acquisition costs were significantly less than AWP, and the OIG found that the acquisition cost/AWP relationship varied depending on the manufacturer, regardless of whether the drug was multi-source. For single-source drugs, invoice costs were 20 percent lower than AWP for purchases directly from the manufacturer and 12 to 18 percent lower than AWP for purchases through oncology wholesalers. For multi-source drugs, invoice prices were between 20 and 83 percent lower than AWP for purchases directly from manufacturers and between 9 and 83 percent lower than AWP for purchases through oncology wholesalers.[30]

15. In late 1992 and early 1993, the GAO conducted a study comparing drug purchase costs and Medicaid reimbursements in Illinois and Maryland and found that all nine pharmacies studied purchased drugs at prices below AWP, with an average discount of 26 percent and a range of discounts of 16 to 42 percent below AWP.[31]

16. A 1993 GAO survey looked at the impact of the Medicaid rebates on prices offered to four Health Maintenance Organizations ("HMOs") and eight hospital group purchasing organizations ("GPOs").[32] The HMOs received average discounts off published list prices of 32 percent in 1990 and 34 percent in 1991. The average discounts for inpatient drugs purchased by the GPOs were 27 percent in 1990 and 28 percent in 1991, while the discounts for outpatient drugs purchased by the GPOs were 29 percent in both years. The discounts to AWP in 1990 ranged from 2 to 99 percent.[33]

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said that information from the *Red Book* was "… meant to approximate the cost to the retailers (pharmacists) only." The officials also "… emphasized that their focus has always been the pharmacy sector" and that the manufacturers who supplied pricing information to the *Red Book* were well aware of this. (Appendix II.)

30 OIG Nov 1992, Appendix III.

31 GAO, *Medicaid Outpatient Drug Costs and Reimbursements for Selected Pharmacies in Illinois and Maryland*, GAO/HRD 93-55FS, March 1993, pp. 5-6.

32 GAO, *Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions*, GAO/HRD-93-43, January 1993 ("GAO Jan 1993"), pp. 1-2.

33 GAO Jan 1993, pp. 18-19.

17. In June 1994, HCFA sent a letter to its regional carriers requesting that they determine EACs for eleven high volume drugs.[34] They noted, "In addition to the EAC, consider allowing an additional fee for the overhead of handling or dispensing drugs. For example, you might determine that an overhead allowance of 10% above the material costs would be equitable in establishing EAC. However, in no case can the cost of the drug plus a dispensing fee exceed the AWP for the drug."[35]

18. In February 1996, the OIG reported that "... Medicare allowed a higher price to drug suppliers [than Medicaid] for two of the three [nebulizer] drugs reviewed because of the manner in which it used the AWP to determine the drug price. This resulted in increased costs to the Medicare program of over $11.7 million."[36] In May 1996, the OIG released a report on pricing of albuterol sulfate that found that 16 percent of retail pharmacies surveyed charged "at least 30 percent less for generic versions of albuterol sulfate than Medicare would have allowed for the same drugs."[37] They also found that pharmaceutical buying groups paid prices that were between 56 and 70 percent less than the Medicare allowance.[38]

19. In September 1996, the OIG issued a report on pharmacy acquisition costs and estimated that AWP exceeded invoice prices by 16.9 percent for branded drugs and 45.2 percent for generic drugs for North Carolina, and by 18.3 percent for branded drugs and 42.5 percent for generic drugs for the nation as a whole.[39]

20. A 1997 study by the OIG revealed that for 22 drugs (mostly PADs), Medicare's reimbursement allowances exceeded actual wholesale prices and that "[t]otal

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34 Letter from M.J. Christenberry, Associate Regional Administrator, Division of Medicare, HCFA Regional Office VI, to All Regional Carriers, "Determination Of Cost Of Drugs—Action," Regional Carrier Letter No. 94-19, June 8, 1994, pp. 1-2.

35 *Ibid.*, p. 4.

36 OIG, *Medicare Payments for Nebulizer Drugs*, OEI-03-94-00390, February 1996, p. 6.

37 OIG, *A Comparison Of Albuterol Sulfate Prices*, OEI-03-94-00392, June 1996, p. 4.

38 *Ibid.*, p. 5.

39 OIG, *Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the North Carolina Department of Human Resources*, A-06-95-00071, September 1996 ("OIG Sep 1996"), p. 1.

allowed charges for the 22 drugs would have been reduced by 29 percent ($447 million of $1.5 billion) if actual wholesale prices rather than AWP were the basis for Medicare reimbursement [in 1996]."[40] The average discount in 1995 was 35 percent,[41] and discounts from AWP in 1995 ranged from 15 to 29 percent for single-source drugs and 45 to 95 percent for multi-source drugs.[42] The 1997 study also revealed that,

> "Although Medicare's reimbursement methodology for prescription drugs does not provide for different payment rates based on geographical factors, the allowed amounts for individual drug codes varied among the carriers. .... For some drug codes, the differences in allowed amounts were significant. Carriers' allowed amounts varied even for single-source drugs where the reimbursement rate is based on only one AWP. A carrier reimbursed code J9217 (leuprolide acetate, a single-source drug) at $496.25 for all of 1995. Another carrier allowed $412.29 for the first quarter of 1995, $439.30 for the second and third quarters, and $477.50 for the fourth. For the first quarter of 1995, providers in one State were receiving 20 percent more in reimbursement than providers billing the same drug code in another State."[43]

21. In 1998, HCFA proposed revising the method of calculating reimbursements for multi-source drugs, noting that the "... AWP for the brand name products was ignored on the presumption that the brand AWP always was higher than the generic AWPs ... while this presumption may have been true when the policy first was promulgated in 1991, it was not always true in 1998."[44] Consequently, the final rule established that "[t]he charge allowed by Medicare for drugs and biologicals would be the lower of 95 percent of the median generic AWP or 95 percent of the lowest brand AWP."[45]

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40 OIG, *Excessive Medicare Payments For Prescription Drugs*, OEI-03-97-00290, December 1997 ("OIG Dec 1997"), p. 7.

41 OIG Dec 1997, p. 7.

42 OIG Dec 1997, Table C-2.

43 *Ibid.*, p. 9.

44 CRS, Memo from Thomas J. Nicola (CRS) to the House Committee on Energy and Commerce regarding Regulatory and Legislative History of Medicare Drug Reimbursement Based on Average Wholesale Price, August 31, 2001 ("CRS Aug 2001"), pp. 2-3.

45 CRS Aug 2001, p. 4.

22. The OIG once again compared Medicare allowances with available pricing information for albuterol sulfate in August 1998 and found that (1) "Medicare allowed up to 333 percent more than acquisition costs available [through GPOs] for albuterol sulfate in 1998" and (2) "Customers of mail-order pharmacies will pay up to 30 percent less than Medicare for albuterol sulfate in 1998."[46]

23. "Late in 1998, HCFA reportedly attempted to use the inherent reasonableness authority … to reduce what it considered excessive reimbursement for several items."[47] Congress suspended this authority in 1999.[48]

24. A provision in BBA 1997 required the Secretary of HHS to report to Congress about the impact of the reduction in the Medicare payment rate on AWPs of drugs covered by Medicare.[49] The Secretary's response ended with the statement, "Conclusions are further obfuscated by the OIG finding cited earlier in this report that, as an unregulated, suggested price, typically set by the manufacturer, the AWP bears no consistent or predictable relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace."[50]

25. In a report entitled "High Cost Drugs Under the Outpatient Prospective Payment System ["OPPS"]" prepared for HCFA, the researchers state, "Average hospital acquisition cost for single-source innovator drugs was found to be 67% of AWP, with a standard deviation of 12%. Multi-source drugs were heavily discounted from AWP, with an average acquisition cost of 42% of AWP, and a standard deviation of 24%. This higher standard deviation reflects the broad distribution of acquisition costs, which ranged from 10% to 85% of AWP."[51] They also state, "Although a few [single-source] drug products had substantial discounts, the

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46 OIG, *Are Medicare Allowances for Albuterol Sulfate Reasonable?*, OEI-03-97-00292, August 1998, p. 8.

47 CRS Aug 2001, p. 5.

48 CRS Aug 2001, p. 5.

49 Donna E. Shalala, Secretary DHHS, *Report to Congress: The Average Wholesale Price for Drugs Covered under Medicare*, 1999, p. 1. The Report was due on July 1, 1999.

50 *Ibid.*, p.8.

51 "High Cost Drugs Under the Outpatient Prospective Payment System," Kathpal Technologies, Prepared under contract by Myers and Stauffer LC, September 8, 1999, p. 4.

overwhelming majority of single source brand name drugs clustered in a uni-modal distribution between 60% and 85% of AWP."[52]

26. In calculating pass-through payments under OPPS, HCFA "… applied the following average ratios of acquisition cost to AWP… .68 for drugs with one manufacturer, .61 for multi-source drugs, and .43 for multi-source drugs with generic competitors."[53]

## V. 2000 TO THE PRESENT

27. Thomas J. Bliley, Chairman of the Committee on Commerce, wrote to Donna Shalala, Secretary of HHS, in May 2000, expressing concern over the "… excessive reimbursements that the Medicare program is paying for certain covered pharmaceuticals and other related products."[54] According to the Chairman, the Committee had conducted its own investigations and found that Medicare paid "… considerably more for certain drugs than the actual average price paid by … wholesalers."[55] In addition, he expressed his deep displeasure with HCFA having failed to remedy the problem of having different carriers reimburse at different rates.[56]

28. In May 2000, First DataBank provided revised AWPs for 51 drugs (*ca.* 400 drug codes) to Medicaid programs. These AWPs were based on wholesale price data collected by the DOJ and the National Association of Medicaid Fraud Control Units in the late 1990s.[57] According to the DOJ, purchasers often received further

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52 *Ibid.*, p. 25.

53 HCFA, "Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services," 65 Fed. Reg. 18434 (April 7, 2000) at 18481. This provision applies to those drugs for which HCFA did not have valid cost data.

54 Bliley Letter to Shalala May 2000, p. 1.

55 Bliley Letter to Shalala May 2000, p. 1.

56 Bliley Letter to Shalala May 2000, p. 2.

57 Congressional Research Service, O'Sullivan, Jennifer, *Medicare: Payments for Covered Prescription Drugs*, May 21, 2002, p. 6.

discounts below the advertised wholesale catalog prices, therefore actual acquisition prices would be even lower.[58]

29. In a report published in June 2000, the OIG showed that the VA median cost for albuterol was 85.1 percent lower than the Medicare allowance (then 95 percent of AWP), with discounts of 48.9 percent for the Medicaid upper limit price, 46.8 percent for the internet pharmacy median price, and 20 percent for the chain pharmacy median price.[59]

30. On September 5, 2000, Senator John Ashcroft introduced a bill, "Cancer Care Preservation Act." Senator Ashcroft expressed concern about the proposed Medicare cuts in outpatient drug reimbursement through use of revised AWPs and discussed the awareness of the cancer community, the GAO and the HCFA of the inadequacy of reimbursement for professional services.[60] The Senator said that the planned cuts in Medicare reimbursement would force physicians to send patients back to the hospital for treatment, but his bill would place restrictions on HCFA's ability to implement any changes to payment for outpatient cancer treatment, unless agreed to by the GAO, MedPAC, and members of the cancer community, and also would require the GAO to conduct a nationwide analysis to determine the appropriate payment rates for cancer services administered to Medicare beneficiaries.[61]

31. The OIG published a report comparing Medicare and Veterans Affairs prices in September 2000.[62] In that report, they stated, "We estimate that Medicare

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58 DHHS, HCFA, Program Memorandum—Intermediaries/Carriers, *An Additional Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program*, Transmittal AB-00-86, September 8, 2000 ("Transmittal AB-00-86"), p. 1.

59 OIG, *Medicare Reimbursement of Albuterol*, OEI-03-00-00311, June 2000, p. 15.

60 Statements on Introduced Bills and Joint Resolutions, By Mr. Ashcroft (for himself, Mr. Hagel, and Mr. Abraham), Statement regarding S. 3003, the Cancer Care Preservation Act, Congressional Record – Senate, September 5, 2000, S8022-8023 ("Ashcroft Statement Sep 2000), p. S8022.

61 Ashcroft Statement Sep 2000, pp. S8022-23.

62 The report, OIG, *Medicare Reimbursement of Prescription Drugs*, OEI-03-00-00310 ("OEI-03-00-00310"), is dated January 2001. A later report, OIG, *Medicare Payments for Prescription Drugs*, Response to Request from Representative W.J. Tauzin, OEI-03-01-00490, June 2001, refers to OEI-03-00-00310 as a September 2000 report.

payments for 24 drugs exceeded actual wholesale prices by $761 million a year. This represents 25 percent of the $3.1 billion Medicare and its beneficiaries reimbursed for these drugs in 1999."[63] The report also looked at the differences in reimbursement rates among carriers, noting that the difference between the low and high reimbursement rates for the J-code J0640 was in excess of 100 percent and the difference exceeded 10 percent for an additional five drugs.[64] The report tabulated reimbursement rates for 10 Medicare carriers for 21 J-codes reimbursed by carriers and 3 J-codes reimbursement by DMERCs.[65]

32. Nancy-Ann Min DeParle, the HCFA administrator, wrote Congress to inform the Congressional Members that HCFA was planning to provide the revised AWPs to the Medicare carriers. She noted that

> "As we have gathered information on many of the drugs reviewed by DOJ, we have concluded that Medicare payments for services related to the provision of chemotherapy drugs and clotting factors used to treat hemophilia and similar disorders are inadequate. Therefore, in addition to instructing carriers not to use the DOJ data for the 17 drugs related to chemotherapy and clotting factors, we plan to take administrative action on chemotherapy administration payments and work with Congress to enact legislation regarding clotting factors."[66]

33. On September 8, 2000, HCFA sent a Program Memorandum to its carriers, authorizing them to use revised AWPs for 32 drugs covered by Medicare.[67] HCFA noted that the DOJ data indicate "… an average wholesale price of $22 for one albuterol sulfate NDC which is substantially less than the $73 average wholesale price in the Redbook and compares to $15 from a GPO."[68] HCFA

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63 OEI-03-00-00310, p. 7. Note: the comparison is between reimbursement (at 95 percent of AWP) and the catalog price.

64 OEI-03-00-00310, pp. 8-9.

65 OEI-03-00-00310, p. 15.

66 Letter to Members of Congress from Nancy-Ann Min DeParle, HCFA Administrator, reproduced in *Medicare Part B Resource: Focused Information for Medicare Part B Providers in Maine, Massachusetts, New Hampshire, and Vermont*, October/November 2000, published by the National Heritage Insurance Company of Hingham, Massachusetts, pp. 17-18.

67 Transmittal AB-00-86, p. 1.

68 Transmittal AB-00-86, p. 1.

withdrew its authorization for the use of the revised AWPs on November 17, 2000.[69]

34. Thomas Bliley, Chair House Committee on Energy, wrote Nancy-Ann Min DeParle, HCFA Administrator, on September 25, 2000, in response to her letter of September 8, 2000, discussing the revised AWPs. He noted,

> "Echoing the previous findings of numerous reports by the Department of Health and Human Services' Office of Inspector General (OIG), the [Commerce] Committee has uncovered substantial evidence that Medicare reimburses health care providers at prices dramatically more than what they actually pay for certain drugs. … 1999 prices for Vancomycin, the Abbot Labs-manufactured antibiotic, which a health care provider could buy for $76.00, but for which the AWP upon which Medicare reimbursement was based was $261.84. Similarly, in 1998 a health care provider could buy Gensia's Etoposide for $14.00, while the AWP used to determine Medicare's reimbursement was $141.97."[70]

35. Legislation passed in 2000 imposed a moratorium on "… any direct or indirect decrease in reimbursement for drugs under the current payment methodology …," effective for drugs distributed after January 1, 2001, and directed the GAO to study Medicare reimbursement for drugs and biologicals and also study whether the practice expense component was adequate compensation for administration of these drugs.[71]

36. In September 2001, the GAO issued a report which found that physicians could obtain Medicare-covered drugs at prices that were below current Medicare payments and that wholesalers and GPOs paid prices below AWP. The GAO found that the average discount from AWP for 16 cancer drugs ranged from 13 to

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69 HCFA, Program Memorandum—Intermediaries/Carriers, *Source of Average Wholesale Price Data in Pricing Drugs and Biologicals Covered by the Medicare Program*, Transmittal AB-00-115, November 17, 2000.

70 Letter from Thomas J. Bliley, Chairman, House Committee on Commerce, to Nancy-Ann Min DeParle, Administrator, HCFA, September 25, 2000, p.3. The AWP discount for Vancomycin was 71 percent, and the AWP discount for Etoposide was 90 percent.

71 CRS Aug 2001, pp. 6-7.

34 percent and that two drugs had discounts of 65 and 86 percent, respectively.[72] For drugs supplied through pharmacies, the average discounts from AWP for five inhalation therapy drugs were 69 to 85 percent, and discounts were 14 and 77 percent for two immunosuppressive drugs.[73]

37. In September 2001, CMS Administrator Thomas A. Scully testified before House Subcommittee members that the CMS, OIG, and other parties had long recognized the shortcomings of AWP-based reimbursement for Medicare. He noted that physicians and other providers acquired drugs for prices less than AWP as they obtained discounts that were not reflected in publications such as the *Red Book*.[74] At the same hearing, William Scanlon, Director Health Care Issues at the GAO, referred to AWP as a price that "… may be neither an average nor what wholesalers charge."[75]

38. In March 2002, CMS Administrator Thomas A. Scully testified before a Senate Committee regarding Medicare pricing. He noted:

> "If we simply went to a market survey where we hired one of our contractors, we have 23 carriers in Part B to make these payments and four durable medical equipment carriers, so there are 27 Medicare carriers that make these payments, the inconsistencies—and if we just picked one, let us say we picked Palmetto, which is Blue Cross of South Carolina, which happens to be both in Part B and in durable medical equipment.
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> If we picked one and just said to them, go out and come up with a consistent price across the country in the median of what we pay, because there is so much variation between contractors. That alone would save $500 million a year.

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72 GAO, *Medicare Payments for Covered Outpatient Drugs Exceed Providers' Cost*, GAO-01-1118, September 2001 ("GAO Sep 2001"), p. 4.

73 GAO Sep 2001, p. 17.

74 Testimony of Thomas A. Scully (CMS), Medicare Drug Reimbursements, Transcript of Hearings before the House of Representatives Energy and Commerce Subcommittees on Oversight & Investigations and Health, September 21, 2001 ("Scully (CMS) Testimony 2001"), p. 88.

75 Testimony of William J. Scanlon, Director, Health Care Issues, GAO, *Medicare Part B Drugs: Program Payments Should Reflect Market Prices*, GAO-01-1142T, September 2001, p. 2.

> That would not even be requiring lowering prices, that would just tell our contractors to go out and basically come up with a consistent policy. That would be $500 million a year."[76]

39. Leslie G. Aronovitz, Director of Health Care-Program Administration and Integrity Issues at the GAO, testified in June 2002 that "…Medicare's payments are often not related to market prices that physicians and suppliers actually pay for the products," noting that, "… two inhalation drugs accounting for most of Medicare payments to pharmacy suppliers had widely available discounts averaging 78 percent and 85 percent from AWP."[77]

40. In 2003, the GAO published a report comparing provider costs of purchasing blood clotting factors with Medicare's reimbursement to those providers. The GAO found that in 2001 and the first quarter of 2002, hemophilia treatment centers ("HTCs") obtained prices that were 35 to 48 percent below AWP.[78] They noted that HTCs obtain these discounts through the Public Health Service 340B program and these prices were not available to all Medicare providers of blood clotting factors.[79] The GAO found that other homecare companies received discounts of 22 to 40 percent off AWP for clotting factors.[80]

41. The Medicare Modernization Act of 2003 mandated that the OIG study the difference between Medicare reimbursement for End Stage Renal Disease ("ESRD") drugs and the acquisition cost of those drugs by dialysis facilities. A 2004 report from the OIG found that "[i]n 2003, the 4 largest dialysis providers paid between 12 percent and 68 percent less than the current Medicare

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76 Testimony of Thomas A. Scully, Administrator, CMS, on *Reimbursement & Access To Prescription Drugs Under Medicare Part B*, before the Senate Finance Committee, Subcommittee on Health, March 14, 2002, p. 8.

77 GAO, Testimony of Leslie G. Aronovitz, *Medicare: Challenges Remain in Setting Payments for Medical Equipment and Supplies and Covered Drugs,* before the Senate Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education and Related Agencies, GAO-02-833T, June 12, 2002, pp. 7-8.

78 GAO, *Medicare—Payment for Blood Clotting Factor Exceeds Providers' Acquisition Cost*, GAO-03-184, January 2003 ("GAO Jan 2003"), p. 10.

79 GAO Jan 2003, p. 13.

80 GAO Jan 2003, p. 10.

reimbursement amount for the 10 drugs we reviewed."[81] The OIG report noted that the manufacturers' Average Sales Prices ("ASPs") as defined under the MMA[82] for these 10 drugs were 17 percent less than Medicare's reimbursement, concluding that "any reimbursement amount set by CMS may still allow some facilities to profit from purchasing drugs, and others to potentially lose money."[83]

42. In December 2004, the GAO published a report that stated, "Medicare payment rates for the 16 drugs we studied will exceed oncologists' estimated costs for acquiring these drugs by 22 percent in 2004 and 6 percent in 2005."[84] The report also states, "Regarding chemotherapy administration services, we estimate that fees for almost every service will increase in both 2004 and 2005 relative to 2003, in some cases in excess of 300 percent."[85]

43. In a June 2005 report that compared ASP and AWP, the OIG stated, "For 2,077 national drug codes with ASP and AWP data, ASP is 49 percent lower than AWP at the median."[86] For single-source drugs, ASP was 26 percent below AWP, for multi-source brand drugs, ASP was 30 percent lower than AWP, and for generic drugs, ASP was 68 percent less than AWP.[87] In a companion report, also published in June 2005, the OIG compared "AMP [used in the calculation of Medicaid rebates] to AWP and WAC for national drug codes (NDC) reimbursed by Medicaid."[88] This study found that AMP is equal to AWP less 59 percent and AMP is equal to WAC minus 25 percent.[89] For single-source drugs, AMP was 23

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81 OIG, *Medicare Reimbursement for Existing End-Stage Renal Disease Drugs*, OEI-03-04-00120, May 2004 ("OIG May 2004"), p. 8.

82 CMS, "Medicare Program; Competitive Acquisition of Outpatient Drugs and Biologicals Under Part B," Interim final rule with comment period," 70 Fed. Reg. 39022 (July 6, 2005).

83 OIG May 2004, pp. 10 and 13.

84 GAO, *Medicare Chemotherapy Payments: New Drug and Administration Fees Are Closer to Providers' Costs*, GAO-05-142R, December 1, 2004, p. 2.

85 *Ibid.*, p. 3.

86 OIG, *Medicaid Drug Price Comparison: Average Sales Price To Average Wholesale Price*, OEI-03-05-00200, June 2005, p. 8.

87 *Ibid.*

88 OIG, *Medicaid Drug Price Comparisons: Average Manufacturer Price To Published Prices*, OEI-05-05-00240, June 2005, pp. i-ii.

89 *Ibid.*, p. 9.

percent lower than AWP, for multi-source brand drugs, AMP was 28 percent below AWP, and for generics, AMP was 70 percent lower than AWP.[90]

[90] *Ibid.*, p. 11.

## APPENDIX B: HISTORY OF MEDICARE PART B

1. The Medicare program was established in July of 1965, with the signing of H.R. 6675 by President Johnson, and over 19 million elderly beneficiaries began receiving coverage a year later.[1] Persons aged 65 or over were offered two forms of coverage under Medicare: Part A, which covered the costs of in-patient hospital and related care, was available to all eligible beneficiaries;[2] Part B was an optional, supplementary medical insurance plan that required payment of a monthly insurance premium.[3]

2. Part B covered physician and surgical services, as well as "[i]n-hospital services of anesthesiologists, pathologists, radiologists, and psychiatrists. Limited dental services. Home health services."[4] In addition to these services, Durable Medical Equipment ("DME"), including DME rentals for home use (such as equipment for dialysis), prosthetic devices, and various diagnostic tests were covered. Through the years, the services offered under Medicare Part B have been expanded.

### I. MEDICARE PART B REFORMS PRIOR TO 1992

3. The Social Security Amendments of 1972 ("SSA 72") expanded coverage to include individuals under the age of 65 with long-term disabilities and individuals with end-stage renal disease ("ESRD").[5]

4. In addition to expanding coverage, the SSA 72 stimulated the use by Medicare beneficiaries of Health Maintenance Organizations ("HMOs").[6] Two methods of

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1 "Medicare: A Timeline of Key Developments," Kaiser Family Foundation, available at http://www.kff.org/medicare/medicaretimeline.cfm ("KFF Timeline").

2 History of the SSA During the Johnson Administration 1963—1968, Medicare—The Development of Medicare ("Medicare History"), p. 2 available at http://www.ssa.gov/history/ssa/lbjmedicare1.html.

3 Medicare History, p. 3.

4 Social Security Bulletin, Annual Statistical Supplement, 2000 ("SSB Statistical Supplement 2000"), p. 43, available at http://www.ssa.gov/history/pdf/hlth_care.pdf.

5 KFF Timeline.

6 Ball, Robert, "Social Security Amendments of 1972: Summary and Legislative History," ("Ball 1997"), p. 6, available at http://www.ssa.gov/history/1972amend.html.

reimbursement for HMOs were established. Under the first, the HMO was "at risk" and payments were made on an incentive capitation basis. This method, which could be used only by established HMOs, permitted the HMO and the Government to share in any savings the HMO achieved in average per capita costs of covered health services.[7] The second method, which was required for newly established HMOs and could be used by any HMO, provided for "interim monthly capitation payments subject to year-end adjustment that reflect[ed] the HMO's actual reasonable costs of providing Medicare-covered services."[8]

5. The Omnibus Reconciliation Act of 1985 ("OBRA 85") required the Department of Health and Human Services to study the Resource-based Relative Value Scale ("RBRVS") system as a potential system to be used for reimbursing physicians.[9] The RBRVS was to rank services on a common scale according to resources used to provide those services.

6. According to HCFA, the Omnibus Reconciliation Act of 1986 ("OBRA 86") took the first steps in establishing a foundation for a hospital outpatient prospective payment system ("OPPS") by requiring fiscal intermediaries to use the Health Care Common Procedure Coding System ("HCPCS") when reporting hospital claims.[10] This coding system enabled hospitals and clinics to provide information on procedures and services offered.

7. While Medicare Part A covered drugs given to patients incident to hospital care, as new physician-administered drug therapies emerged that were suitable for outpatient or home-based administration, Part B coverage was expanded several times.[11] Prescription drugs for which Medicare Part B pays are identified by HCPCS Level II codes, including J codes (injectable drugs or drugs used with

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7 Ball 1997, p. 25.

8 Ball 1997, p. 25.

9 GAO, *Medicare Physician Payments: Need to Refine Practice Expense Values During Transition and Long Term*, GAO/HEHS-99-30, February 1999 ("GAO Feb 1999"), p. 28.

10 63 Fed. Reg. 47554 (September 8, 1998).

11 See Shih, Ya-Chen Tina, "Effect of Insurance on Prescription Drug Use by ESRD Beneficiaries," *Health Care Financing Review*, Spring 1999, ("Shih 1999") p. 40.

DME), K codes (immunosuppressive drugs), Q codes (ESRD drugs), A codes (drugs used for diagnostic imaging), and numeric codes (immunizations).[12]

8. Prior to 1987, Medicare reimbursements for medical supplies and outpatient drugs were based on provider charges. Medicare carriers, the private insurance companies who administered Medicare on behalf of HCFA, adjusted their reimbursement payments to providers according to market prices by gathering pricing information from local markets.[13] In 1987, Congress and HCFA changed the method of reimbursement to "Statewide fees [that] were determined on the basis of average supplier charges on Medicare claims allowed in each state in 1986 and 1987."[14]

9. One Section of the Omnibus Budget Reconciliation Act of 1987 ("OBRA 87") directed the Secretary of HHS to report to Congress "on possible modifications to the Medicare Part B payment policy to more appropriately reflect the costs associated with providing chemotherapy to patients in physicians' offices."[15] In its Notice of Request for Comments, HCFA said,

> "Changes in treatment methods and advances in technology now allow chemotherapy to be furnished to many patients in the physician's office, thus reducing the need for hospitalization to administer chemotherapy. Furnishing these services in the physician's office is more convenient for some patients and may provide other benefits as well. Current Medicare Part B payment rules for physicians' services, however, may fail to compensate adequately for these services because the usual reasonable charge payment methodology may not fully recognize the overhead costs involved in these procedures. Some sources of additional costs include employment of nurse oncologists, special patient rooms, and safety

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12 OIG, *Appropriateness of Medicare Prescription Drug Allowances*, OEI-03-95-00420, May 1996 ("OIG May 1996"), p. 3.

13 GAO, *Medicare—Challenges Remain in Setting Payments for Medical Equipment and Supplies and Covered Drugs*, Testimony of Leslie G. Aronovitz, GAO-02-833T, June 12, 2002 ("Aronovitz (GAO) Testimony June 2002"), p. 5.

14 Aronovitz (GAO) Testimony June 2002, p. 5.

15 53 Fed. Reg. 39644 (October 11, 1988).